

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Benylin Chesty Coughs (Original)

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:-

Diphenhydramine hydrochloride	14.0	mg
L-menthol	2.0	mg

## 3 PHARMACEUTICAL FORM

Syrup.

A clear red syrup

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

BENYLIN CHESTY COUGHS (ORIGINAL) is indicated for the relief of cough and associated congestive symptoms.

### 4.2 Posology and method of administration

For oral use

#### **Adults and Children aged 12 years and over:**

One 10 ml dose of syrup 4 times a day.

Maximum daily dose: 40 ml syrup.

#### **Children under 12 years:**

Benylin Chesty Coughs (Original) is contraindicated in children under the age of 12 years (see section 4.3).

### **The Elderly:**

As for adults above (see Pharmacokinetics - The elderly).

#### Hepatic dysfunction

Caution should be exercised if moderate to severe hepatic dysfunction is present (see Pharmacokinetics - Hepatic dysfunction).

#### Renal dysfunction

It may be prudent to increase the dosage interval in subjects with moderate to severe renal failure (see Pharmacokinetics - Renal dysfunction).

Do not exceed the stated dose.

Keep out of the reach and sight of children.

### **4.3 Contraindications**

BENYLIN CHESTY COUGHS (ORIGINAL) is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

Benylin Chesty Coughs (Original) is contraindicated in individuals with chronic or persistent cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by the physician.

Benylin Chesty Coughs (Original) should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOI) or those patients who have received treatment with MAOIs within the last two weeks.

Not to be used in children under the age of 12 years.

### **4.4 Special Warnings and Precautions for Use**

This product may cause drowsiness. If affected individuals should not drive or operate machinery.

Subjects with moderate to severe renal or hepatic dysfunction or urinary retention should exercise caution when using this product (see Pharmacokinetics - Renal/Hepatic Dysfunction).

This product contains diphenhydramine and therefore should not be taken by individuals with narrow-angle glaucoma or symptomatic prostatic hypertrophy.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

#### **4.5. Interactions with other medicinal products and other forms of interaction**

This product contains diphenhydramine and therefore may potentiate the effects of alcohol, codeine, antihistamines and other CNS depressants.

As diphenhydramine possesses some anticholinergic activity, the effects of anticholinergics (eg, some psychotropic drugs and atropine) may be potentiated by this product. This may result in tachycardia, dry mouth, gastrointestinal disturbances (eg, colic), urinary retention and headache.

#### **4.6. Pregnancy and Lactation**

Although diphenhydramine has been in widespread use for many years without ill consequence, it is known to cross the placenta and has been detected in breast milk. BENYLIN CHESTY COUGHS (ORIGINAL) should therefore only be used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

#### **4.7. Effects on Ability to Drive and Use Machines**

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

#### **4.8. Undesirable Effects**

Side effects associated with the use of BENYLIN CHESTY COUGHS (ORIGINAL) are uncommon.

Diphenhydramine may cause: drowsiness; dizziness; gastrointestinal disturbance; dry mouth; nose and throat; difficulty in urination or blurred vision.

Less frequently it may cause palpitations, tremor, convulsions or paraesthesia.

Hypersensitivity reactions have been reported, in particular, skin rashes, erythema, urticaria and angioedema.

Adverse reactions to menthol at the low concentration present in BENYLIN CHESTY COUGHS (ORIGINAL) are not anticipated.

#### **4.9. Overdose**

##### Symptoms and signs

The symptoms and signs of BENYLIN CHESTY COUGHS (ORIGINAL) overdose may include drowsiness, hyperpyrexia and anticholinergic effects. With higher doses, and particularly in children, symptoms of CNS excitation including hallucinations and convulsions may appear; with massive doses, coma or cardiovascular collapse may follow.

##### Treatment

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with Syrup of Ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal may be useful. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Diphenhydramine possesses antitussive, antihistaminic and anticholinergic properties. Experiments have shown that the antitussive effect (resulting from an action on the brainstem) is discrete from its antihistaminic effect. The duration of activity of diphenhydramine is between 4 and 8 hours. Menthol has mild local anaesthetic and decongestant properties.

#### **5.2. Pharmacokinetic Properties**

##### **Absorption**

Diphenhydramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hours.

##### **Distribution**

Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.

## **Metabolism and Elimination**

Diphenhydramine undergoes extensive first pass metabolism. Two successive N-demethylations occur, with the resultant amine being oxidised to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. Menthol is hydroxylated in the liver by microsomal enzymes to p-methane-3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the Glucuronide.

## **The Elderly**

Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

## **Renal Dysfunction**

The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

## **Hepatic Dysfunction**

After intravenous administration of 0.8 mg/kg Diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.

### **5.3. Preclinical Safety Data**

#### **Mutagenicity**

The results of a range of tests suggest that neither diphenhydramine or menthol have mutagenic potential.

#### **Carcinogenicity**

There is insufficient information to determine the carcinogenic potential of diphenhydramine or menthol, although such effects have not been associated with these drugs in animal studies.

#### **Teratogenicity**

The results of a number of studies suggest that the administration of either diphenhydramine or menthol does not produce any statistically significant teratogenic effects in rats, rabbits and mice.

#### **Fertility**

There is insufficient information to determine whether diphenhydramine has the potential to impair fertility, although a diminished fertility rate has been observed in mice in one study.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of Excipients**

Ammonium chloride  
Liquid Glucose  
Sucrose  
Ethanol 96%  
Glycerol  
Sodium citrate  
Saccharin sodium  
Citric acid monohydrate  
Sodium benzoate  
Caramel T12  
Raspberry flavour 503.850/T  
Carbomer  
Ponceau 4R (E124)  
Purified water

### **6.2. Incompatibilities**

None known

### **6.3. Shelf life**

2 years

### **6.4. Special Precautions for Storage**

Do not store above 25°C

### **6.5 Nature and contents of container**

125, 150 or 300ml amber glass bottles with a 2 piece or a 3 piece plastic child resistant, tamper evident closure fitted with a polyterephthalate ethylene faced aluminium/expanded polyethylene laminated wad

**6.6. Instructions for Use, Handling and Disposal**

None applicable

**7 MARKETING AUTHORISATION HOLDER**

McNeil Products Limited  
Foundation Park  
Roxborough Way  
Maidenhead  
Berkshire SL6 3UG  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER(S)**

PL 15513/0048

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21/03/2006

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30/07/2014